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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/961,058	09/24/2001	John J. Schlager	RICD 00-21	5204

7590

01/30/2004

ATTN: MCMR-JA (Ms. Arwine)
Office of the Staff Judge Advocate
U.S. Army Medical Research and Materiel Command
504 Scott Street
Ft. Detrick, MD 21702

EXAMINER

ZEMAN, MARY K

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/961,058

Applicant(s)

SCHLAGER ET AL.

Examiner

Mary K Zeman

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-11, 13-15 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-11, 13-15 and 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Art Unit: 1631

DETAILED ACTION

Claims 1-7, 9-11, 13-15 and 18-20 are pending in this application.

Applicant's arguments filed 10/14/03 have been fully considered but they are not persuasive. Any rejection not repeated below, has been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 9-11, 13-15 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burland (2000) in view of Smith et al. (1993).

Applicant has questioned the publication date of the applied Burland reference. The publisher has provided the publication date for the print version of Methods in molecular biology vol. 132, Bioinformatics methods and protocols, Humana press Inc. as **August 26, 1999**. Therefore, the publication date is even earlier than that cited previously by the examiner.

Applicant argues that the program discussed by Burland is not intended for batch processing of unknown sequences. This is not persuasive, as Burland indicates that the methods can be performed multiple times in succession. The rejected claims do not set forth specific batch processing steps- merely that a plurality of sequences are processed, which is disclosed and suggested by Burland. Automation of a routine step is not a reason for non-obviousness. Applicant also argues that Burland does not provides for the automatic generation of spreadsheets containing specific information. This is not persuasive, as the mere automation of a known step does not render that step non-obvious. (See, MPEP 2106; *Dann v. Johnston*, 425 U.S. 219, 227-30, 189 USPQ 257, 261 (1976); *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958).)

Burland (Burland, T. Methods in Molecular Biology (2000) Vol. 132: Bioinformatic methods and protocols, pages 71-91.) discusses the commercial computer product Lasergene,

Art Unit: 1631

version 4.0, available from DNASTar in 1999, and a method of using the product. This program allows for the inputting of raw sequences, which can be done electronically. The sequence can then be automatically trimmed, based on various user inputs, or the use of default settings. This information is saved in files of various formats. The sequence can be further edited. The sequence is searched against databases (such as the database of NCBI) containing nucleic acid sequences using BLAST. The limitations of claim 11 are standard results from a BLAST query. The results are returned to the user in a format which can be a spreadsheet, or combine graphical information with the spreadsheet. Information from the first set of results can be selected and placed in a second spreadsheet. Various search strategies and implementations are discussed.

Burland does not disclose the specific best match scoring algorithm used in the claimed trimming interface as set forth in step (c) of claim 1.

Smith et al. (Smith et al. BioTechniques 1993, vol. 14, no. 6 pages 1014-1018) discloses the use of a best match algorithm in the trimming of known vector sequences from a polynucleotide sequence. The trimming interface of Smith is specifically intended for automated processing of large amounts of nucleic acid sequences. Smith discloses that the user indicates the percentage of bases in the cloning vector sequence that must match the bases at the head or at the tail of a fragment sequence- and then the vector sequences are trimmed from that sequence. This appears to meet the limitations of the trimming step.

It would have been obvious to one of skill in the art at the time the invention was made to have used a best match scoring algorithm of Smith in the trimming interface of Burland. This type of algorithm allows for minimal human intervention in the processing of sequences, and is more accurate.

One of ordinary skill in the art at the time the invention was made would have been motivated to use this type of trimming interface, as it requires little human input and makes the batch processing of numerous sequences easier and less time-consuming. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

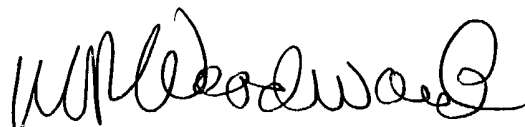
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272-0723.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (571) 272-0722.

The Official fax number for this Art Unit is: (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC1600 Receptionist whose telephone number is (703) 308-0196.

mkz
1/23/04


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